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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,089	03/08/2001	David R. Phillips	44481-5008-02	7657

7590 04/23/2003
INTELLECTUAL PROPERTY GROUP
MILLENNIUM PHARMACEUTICALS, INC
75 SIDNEY STREET
CAMBRIDGE, MA 02139

EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/23/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/801,089

Applicant(s)
Phillips et al.

Examiner
G.R. Ewoldt

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-13 and 29, drawn to methods of blocking integrin-mediated signaling, classified in Class 514, subclasses 2 and 8.

II. Claims 14-20, drawn to methods of identifying agents which block integrin-mediated signaling, classified in Class 435, subclass 7.1.

III. Claims 21-23, drawn to methods of identifying integrin mediated signaling by determining phosphorylation, classified in Class 435, subclass 7.1.

IV. Claims 24-26, drawn to methods of identifying integrin signaling partners, classified in Class 435, subclass 7.1.

V. Claims 27-28, drawn to isolated peptides, classified in class 530, subclass 300.

2. Inventions V and I/II/IV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as affinity purification procedures or detection assays or diagnostic assays or as an antigen to generate antibodies or in the inventions of I/II/IV.

3. Inventions I/II/IV are different methods of use. These inventions require different ingredients, process steps and endpoints to accomplish the use of peptides. Therefore they are novel and unobvious in view of each other and are patentably distinct.

4. Inventions V and III are not related as products and a method of use. Therefore, they are novel and unobvious in view of each other and are patentably distinct.

5. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-V is not required for any other group from Groups I-V, and Groups I-V have acquired a separate status in the art because the searches are not co-extensive and the invention encompass divergent subject matter, restriction for examination purposes as indicated is proper.

6. Should Applicant elect Group I, Applicant is further required under 35 U.S.C. § 121 to elect: a **specific** "agent which blocks the binding of said signaling partner", a **specific** β integrin subunit, a **specific** "signaling partner", and a **specific** "pathological state" (if a method for reducing the severity of said state is part of the elected species), and list all Claims readable thereon including those subsequently added. Currently all claims are generic.

7. Should Applicant elect any of Groups II, IV, or V, Applicant is further required under 35 U.S.C. § 121 to elect a **specific** β integrin subunit peptide, and list all Claims readable thereon including those subsequently added. Currently all claims are generic.

8. Note that any elected agents or peptides comprising specific sequences **must** be identified by SEQ ID NO:.

9. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or

admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. The different agents, signaling partners, β integrin subunits, and β integrin subunit peptides are distinct because their structures and modes of action are different, i.e., they are different chemical compositions with different structures and functions. Because the sequences differ with respect to their structure, a person of ordinary skill in the art would not envision one in view of the other. The pathological state species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints. Accordingly the species are separate and patentably distinct in view of each other.

12. Any inquiry concerning this communication from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Technology Center 1600 at 703-872-9306 (before final) and 703-872-9307 (after final).



G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
April 23, 2003